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09/160,635	09/24/1998	VERNON WONG	A-60179-2/DJ	6584

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

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Please find below and/or attached an Office communication concerning this application or proceeding.

Art Unit: 1616

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10, 18, 19, 20, 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5869079. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass those of the patent. As to the second therapeutically active agent it would be obvious to add a second therapeutic agent with similar activity to obtain the beneficial effect of both agents. *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 18-20, 22, 25, 28 rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 474098 in view of Drost et al.

EPA '098 teach a controlled release composition comprising a hardly soluble drug, a water-soluble macromolecule and a biodegradable macromolecule (abstract). Dexamethasone, hydroxypropylcellulose and copolymer of lactic acid and glycolic acid are specified (page 2 line 46-page 3 line 1). Disks and sheets are disclosed (page 3 lines 26-27). 30% of each is disclosed. (Table page 4).


Drost et al teach that hydroxypropylmethylcellulose and hydroxypropyl cellulose are equivalent water soluble polymers (column 2 lines 49-50).

It would have been obvious to one of ordinary skill to make a composition comprising a hardly soluble drug, a water soluble polymer, and a biodegradable polymer to achieve the beneficial effect of controlled release in view of EPA '098. As to the claimed hydroxypropylmethylcellulose, Drost et al teach that it is equivalent to the hydroxypropylcellulose as a water soluble polymer. As to the claimed second active agent, it would be an obvious expedient to add a second agent with activity similar to the first to achieve the beneficial effect of both, as recited in the ODP rejection.

Claims 10, 18-20, 22, 23, 25, 28 rejected.

Claims 16, 17, 24, 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.


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